REMARKS

Claims

Claims 1-19, 24–26 and 29–38 are pending with claims 1–19 withdrawn from consideration and claims 20–23 and 27–28 cancelled without prejudice or disclaimer.

Claim Amendments

Claims 23–24 have been amended. Support for the amendment may be found in the specification as originally filed. See, for example, page 7, lines 30–31. It is submitted that the claim amendments do not add new matter.

Rejections under 35 U.S.C. § 112, first paragraph (written description)

Claims 24–26, 29–33, 35–38 stand rejected under 35 U.S.C. §112, first paragraph as allegedly lacking a written description. Applicants respectfully traverse the rejection.

At the outset, it is submitted that the scope of the compounds claimed herein are adequately described in the specification. Applicants' specification provides detailed description of the structural features of the claimed compounds. For example, a skilled worker may refer to the sequence listing page or pages 2–3 of the instant specification for structures of compounds (i.e., polypeptides) recited in the claims. Methods for obtaining the claimed compounds are routine for one of ordinary skill in the art. For example, a skilled artisan can readily appreciate that the claimed polypeptides may be routinely generated using well known conventional techniques from molecular biology and/or synthetic chemistry. Furthermore, Applicants' disclosure, along with the references cited therein, provides relevant techniques for testing the polypeptide compounds. For example, the paragraphs bridging pages 2 and 3 of the instant specification provide expressed written guidance on the ability of the claimed compounds to bind to and further modulate Hsp47 activity. Reagents (for example, cell-lines, vectors, and detection reagents) and/or tools, which may be utilized for the study of Hsp47 activity, are also discussed. Moreover, the specification provides expressed

written guidance on a role of Hsp47 molecules in cellular physiology, and how functional modulation of Hsp47, comprising, for example, binding of the claimed polypeptides to Hsp47 molecules in the cellular setting, is useful in the treatment of diseases. A list of compounds which are commensurate with this scope is also provided.

The Office Action at page 2 alleges that "the sequence motif of SEQ ID NO:1 encompasses more than that is represented by sequence such as SEQ ID NOS: 9 and 13." Applicants courteously disagree with this contention. The PTO's contention underestimates the state of the art at the time the Application was filed. Contrary to the Examiner's assertion, Applicants respectfully submit that it is not necessary to describe every member of the genus being claimed.

See, e.g., *In re Angstadt*, 537 F.2d 498, 190 USPQ 214 (CCPA 1976). While the rejection in *Angstadt* was an enablement rejection, i.e., sufficiency of disclosure, the Federal Circuit cited *Angstadt* in *Capon v. Eshhar*, 418 F.3d at 1357, 76 USPQ2d 1078 (CA FC 2005), in the context of a lack of written description rejection. In *Capon,* the Federal Circuit held that the Board had erred in making a rejection for lack of written description requirement because the specification did not describe the structure or set forth a formula or chemical name for the nucleotide sequences of claimed chimeric genes.

The disclosure in applicants' specification more than reasonably conveys to one of ordinary skill in the art that applicants' hade possession of the claimed subject matter as of the filing date. The amino acid sequence of SEQ ID NO:1 is essentially a chemical structure, and the skilled biochemist/molecular biologist would appreciate that any position identified as X in SEQ ID NO:1 has twenty possible identities each of which is known (since there are 20 naturally occurring amino acid residues that are incorporated into peptides and polypeptides). Therefore, the skilled biochemist/molecular biologist could easily envision every one of the dodecapeptides that falls within the scope of the claims as presently amended.

As discussed in the aforementioned paragraph, the skilled worker could use routine techniques, for example, recombinant expression techniques or synthetic chemistry, to generate members of the claimed genus of compounds. Methods for testing the activity of the compounds, for example, in relation to binding to claimed Hsp47 molecule and modulating the activity of said Hsp47 when bound thereto, are also

outlined in the Examples. Thus, nothing more than routine experimentation would be required. In short, the claims in the current form, with adequate support from the specification, fully comply with the statutory requirements under 35 U.S.C. § 112, first paragraph, as specified in the PTO's own guidelines.

The Office Action contends at page 5 that "the specification does not provide…a core structure of amino acids, characteristics [thereof], and further fails to describe a representative number of species." However, it is submitted that the detailed disclosure contained in Applicants' specification fully satisfies the stated criteria. The Patent Office has failed to provide sufficient evidence to support its contention that Applicants' claimed polypeptide species, for example, SEQ ID NOS: 9 and 13, fail to encompass the structural and functional characteristics of the compounds claimed herein. The Patent Office's contention is especially weak given the mature state of the art at the time the application was filed.

It is therefore respectfully submitted that the rejection under Section 112, first paragraph should be withdrawn.

Rejections Under 35 U.S.C. §102(b)

The rejection of claims 24–26 and 29–31 under 35 U.S.C. §102 (b) as allegedly anticipated by Bayer et al. (Peptides: Chem, Biochem., Proc. Amer. Peptide Symp., 1st Meeting (1970)) is respectfully traversed.

The Office Action contends that Bayer's isolated dodecapeptide of AFAFAFAFAFAF anticipates the compounds claimed by the instant invention. In view of Applicants' amendment of the claims, it is respectfully submitted that the pending rejection is moot. More specifically, the peptide taught by Bayer comprises an Alanine (A) residue at position 3 and at position 11, which falls outside the scope of the currently claimed peptide compounds. Compare Applicants' amended claims 23 and 24.

Bayer does not describe or suggest the structual and/or functional characteristics of the claimed polypeptide compounds. Thus, the cited reference neither anticipates nor renders obvious what is claimed herein. Withdrawal of the rejection is respectfully requested.

A check in the amount of $120.00 is enclosed for the one-month extension-of-time fees. No other fee is believed to be due, however, the Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

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